

REMARKS

I. Status of the Claims

Applicants respectfully request reconsideration of the present application in view of the foregoing amendments and in view of the reasons that follow.

Claims 24, 27, 33, 38, and 47 are currently being amended. These claims are being amended to correct editorial errors, such as spelling errors and improper antecedent basis. These amendments are not intended to narrow the scope of the claims in any way.

This amendment adds, changes and/or deletes claims in this application. A detailed listing of all claims that are, or were, in the application, irrespective of whether the claim(s) remain under examination in the application, is presented, with an appropriate defined status identifier.

Because the foregoing amendments do not introduce new matter, entry thereof by the Examiner is respectfully requested. Upon entry of this Amendment, claims 23-33, 35-47, and 49-58 will remain pending in the application.

II. Claim Objections

Claim 24 is objected to by the Examiner because it recites the phrase “bacterial organism” in the singular tense and depends from claim 23 which recites the phrase “bacterial organisms” in the plural tense. Office Action at page 5. Applicants have amended claim 24 to recite “bacterial organisms” in the plural tense. This ground for objection is moot.

Claim 27 is objected to by the Examiner because it recites “freundii” instead of “freundii.” Office Action at page 5. Applicants have amended claim 27 to recite “freundii.” This ground for objection is moot.

Claims 28 and 42 are objected to because there is allegedly no antecedent support in claims 24 and 42, from which claims 28 and 42 respectively depend, for the term “*Klebsiella oxytoca*.” Office Action at page 5. Applicants have amended claims 24 and 38 to recite the

term “*Klebsiella oxytoca*.” Exemplary support for this amendment is found in the specification on page 11, line 9. This ground for objection is moot.

Claims 33(f) and 47(f) are objected to because the claims recite “resistant to resistant to.” Office Action at page 5. Applicants have amended claims 33(f) and 47(f) to recite “resistant to.” This ground for objection is moot.

Claim 38 is objected to because there is allegedly no antecedent basis for the term “bacterial organisms” in claim 37 from which claim 38 depends. Office Action at page 6. Claim 38 has been amended to recite “wherein the bacterial infection is caused by . . .”, which is consistent with the language used in claim 37. This ground for rejection is moot.

Applicants respectfully request reconsideration and withdrawal of the claim objections described above.

III. Claim Rejections - 35 U.S.C. § 102

A. Rejection of claims 23-25, 33, 37-39 and 47 as being allegedly anticipated by Norris (U.S. Patent No. 4,957,686)

Claims 23-25, 33, 37-39, and 47 are rejected by the Examiner under 35 U.S.C. § 102(b) as being allegedly anticipated by U.S. Patent No. 4,957,686 to Norris (“Norris”). Applicants respectfully traverse the rejection and request reconsideration and withdrawal thereof.

The basis of the Examiner’s rejection is that although Norris does not teach or suggest a bacteriophage capable of infecting more than one strain of *S. sanguis*, this does not preclude the bacteriophage of Norris from being able to infect more than one strain of *S. sanguis*. Applicants remind the Examiner that for a claim to be anticipated by a reference under 35 U.S.C. § 102, each and every element set forth in the claim must be found, either expressly or inherently, in the reference. If the reference fails to teach or suggest even one limitation of the claimed invention, then the claim is not anticipated. *Atlas Powder Co. v. E.I. duPont de Nemours & Co.*, 750 F.2d 1569, 1574 (Fed. Cir. 1984).

Norris does not teach or suggest a bacteriophage capable of infecting more than one strain of *S. sanguis*. There is no disclosure in Norris that would indicate that the bacteriophage of Norris has a wide host range. For example, Norris does not teach serial isolation of phage preparations, by which the virulence of a phage can be dramatically increased. Applicants request that the Examiner provide evidence that the bacteriophage of Norris meets each and every limitation of the present claims. In the absence of such evidence, withdrawal of the rejection is respectfully requested.

**B. Rejection of claims 23-24, 27, 29, 33, 37-38, 41, 43 and 47
as being allegedly anticipated by EP 0414304 to Unilever**

Claims 23-24, 27, 29, 33, 37-38, 41, 43, and 47 are rejected by the Examiner under 35 U.S.C. § 102 (b) as being allegedly anticipated by EP 0414304 to Unilever ("Unilever '304"). Applicants respectfully request reconsideration and withdrawal of the rejection.

Unilever '304 is directed to compositions comprising oral, skin, or faecal bacteriophages. The bacteriophage compositions were obtained by screening a raw sample with a bacterial sample to identify a phage "specific for the [bacterial] microorganism." *See* col. 5, lines 9-14; and col. 6, lines 6-10, of Unilever '304. The bacteriophage was then tested against the bacteria it was cultured against to test the effectiveness of the bacteriophage composition. *See* col. 6, lines 17-28, of Unilever '304. In sum, all of the bacteriophages prepared according to the method have limited host specificity.

Moreover, this reference does not teach Applicants' claimed purified, virulent, non-toxic, host-specific bacteriophage preparations having a wide host range. Unilever '304 does not teach *serial isolation* of phage preparations, by which the virulence of a phage can be dramatically increased. For at least these reasons, Unilever '304 does not teach or suggest the claimed invention.

**C. Rejection of claims 23-24, 27, 29, 33, 37-38, 41, 43
and 47 as being allegedly anticipated by EP 0403292 to Day et al.**

Claims 23-24, 27, 29, 33, 37-38, 41, 43 and 47 are rejected by the Examiner under 35 U.S.C. § 102 (b) as being anticipated by EP 0403292 to Day et al. ("Day '292.") Applicants respectfully request reconsideration and withdrawal of the rejection.

Day '292 is directed to bacteriophage preparations used to prevent the growth of hygienically undesirable bacteria. *See* col. 2, lines 18-23 and 32-40, of Day '292. Day '292 also teaches that "[p]hages can usually be isolated from cultures of the bacteria to which they are specific." *See* col. 4, lines 33-34, of Day '292.

Day '292 does not teach the claimed purified, virulent, non-toxic, host-specific bacteriophage preparations having a wide host range. Day '292 does not teach serial isolation of phage preparations, by which the virulence of a phage can be dramatically increased. Moreover, the Examples of Day '292 are limited to isolating phage specific for a single strain of bacteria. Examples 1 and 2 teach inoculating plates or broths with one of the listed organisms, Examples 8-10 refer to isolation of a phage specific for one of the listed three organisms, and Example 11 refers to isolation of a phage specific for one organism - *Staphylococcus epidermis*. *See* col. 5, lines 4-7 and 31-35; col. 6, lines 37-47; and col. 6, line 56, through col. 7, line 4, of Day '292.

**D. Rejection of claims 23, 35, 37 and 49 as Being
Allegedly Anticipated by SU 827064 to Golosova et al.**

Claims 23, 35, 37, and 49 are rejected by the Examiner under 35 U.S.C. § 102 (a) as being anticipated by SU 827064 to Golosova et al. ("Golosova '064"). Applicants respectfully request reconsideration and withdrawal of the rejection.

Golosova '064 is directed to a method for preventing Gram-negative bacterial infections in patient undergoing acute leucosis therapy by restoring normal microflora of the intestinal tract using bacteriophages.

Golosova '064 fails to teach the claimed purified, virulent, non-toxic, host-specific bacteriophage preparations having a wide host range. Golosova '064 does not teach *serial isolation* of phage preparations, by which the virulence of a phage can be dramatically increased. Therefore, the claims are not anticipated by the disclosure of Golosova '064.

IV. Claim Rejections - 35 U.S.C. § 103

Claims 23-30, 33, 35-44, 47 and 49-50 are rejected by the Examiner under 35 U.S.C. § 103 as being obvious over GB 2253859 to Day et al. ("Day '859") in view of U.S. Patent No. 5,688,501 to Merrill ("Merril"). Applicants respectfully traverse and request reconsideration and withdrawal of the rejection.

The combined teachings of Merrill and Day '859 do not disclose each and every limitation of the claimed invention. Therefore, the present invention is not obvious over Day '859 in view of Merrill.

A. Day '859 does not teach the claimed purified, virulent, non-toxic, host-specific bacteriophage preparations having a wide host range

Day '859 discloses utilizing a bacteriophage in an area where food is prepared or stored to treat or prevent bacterial infection in the food. *See, e.g.*, page 2, fourth full paragraph. Day '859 does not teach the claimed purified, virulent, non-toxic, host-specific bacteriophage preparations having a wide host range. For example, Day '859 fails to teach serial isolation of phage preparations, by which the virulence of a phage can be dramatically increased. In the first full paragraph on page 9 of the outstanding Office action, the Examiner recognizes that Day '859 does not teach bacteriophage having a broad host range, by stating that Day '859 fails to show "bacteriophages for additional species of bacterial pathogens." Additionally, in the first full paragraph on page 9 the Examiner recognizes that Day '859 fails to "show the combination of at least two bacteriophages together with an antibiotic."

B. Merrill does not overcome the deficiencies of Day '859

Merril does not overcome the deficiencies of Day '859. Merrill fails to teach:
(a) virulent bacteriophage having a broad host range, and (b) a virulent bacteriophage preparation comprising two or more bacteriophage strains.

The Examiner asserts that at col. 7, lines 34-35, Merrill teaches virulent bacteriophages having a broad host range, albeit using "different terminology." The terminology at col. 7, lines 34-35, does not disclose that the bacteriophage of Merrill have a broad host range. Instead, col. 7, lines 34-35, of Merrill merely prefaces the list of bacterial "species and strains" disclosed in col. 7, line 37, through col. 8, line 45, that "represent the greatest threat to mankind." See col. 7, lines 35-36. No where in Merrill is a bacteriophage having a broad host range taught or suggested.

Furthermore, with respect to the Examiner's contention that Merrill suggests and teaches combinations of two or more bacteriophage strains, the passage cited by the Examiner fails to teach or suggest a bacteriophage preparation comprising two or more bacteriophage strains. The Examiner asserts that the term used by Merrill to teach the combination of two or more bacteriophages is the word "adjunctive." The Examiner consulted a dictionary to determine the definition of the term "adjunctive" and assigned this term a broad definition. However, the meaning of the term "adjunctive" is provided in the Merrill disclosure and it is this definition of the term that must be applied.

The embodiment of Merrill involving using the bacteriophage as a stand-alone therapy or as an adjunctive therapy is described in the paragraph bridging columns 8 and 9 as follows:

"The anti-HDS modified bacteriophage of the present invention can be used as a stand-alone therapy or as an adjunctive therapy for the treatment of bacterial infections. Numerous antimicrobial agents (including antibiotics and chemotherapeutic agents) are known in the art which would be useful in combination with anti-HDS modified bacteriophage for treating bacterial infections. Examples of suitable antimicrobial agents and the bacterial infections which can be treated with the specified antimicrobial agents are listed below. However, the present invention is not limited to the

antimicrobial agents listed below as one skilled in the art could easily determine other antimicrobial agents useful in combination with anti-HDS modified bacteriophage."

It is evident from this passage that adjunctive therapy as contemplated by Merrill does not involve a bacteriophage preparation comprising two or more bacteriophage strains. Instead, such therapy contemplates administering antimicrobial agents, such as antibiotics and chemotherapeutic agents, in conjunction with the disclosed bacteriophage.

For the reasons described above, the present invention is not obvious in view of the combined disclosures of Day '859 and Merrill.

CONCLUSION


The present application is now in condition for allowance. Favorable reconsideration of the application as amended is respectfully requested.

The Examiner is invited to contact the undersigned by telephone if it is felt that a telephone interview would advance the prosecution of the present application.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741. If any extensions of time are needed for timely acceptance of papers submitted herewith, Applicant hereby petitions for such extension under 37 C.F.R. §1.136 and authorizes payment of any such extensions fees to Deposit Account No. 19-0741.

Respectfully submitted,

Date March 10, 2004

By 

FOLEY & LARDNER LLP
Customer Number: 22428

22428

PATENT TRADEMARK OFFICE

Telephone: (202) 672-5538

Facsimile: (202) 672-5399

Michele M. Simkin
Attorney for Applicant
Registration 34,717